## **Program Assessment Rating Tool (PART) Summary**

Food and Drug Administration FY 2004–2006

(Dollars in Millions)						
FY 2004 PARTs**	FY 2004 Enacted	FY 2005 Appropriation	FY 2006 Request	Narrative Rating		
FDA's Five Centers were evaluated: Center for Biologic Evaluation & Research Center for Devices & Radiological Health Center for Drug Evaluation & Research Center for Food Safety & Applied Nutrition Center for Veterinary Medicine				All received Results not Demonstrated		

<sup>\*\*</sup>No resources are shown because OMB decided in the FY 2005 PART process to evaluate FDA as a whole entity and not as separate components as in the FY 2004 PART.

FY 2005 PARTs	FY 2004 Enacted	FY 2005 Appropriation	FY 2006 Request	Narrative Rating
Food and Drug Administration	\$1,800,541,000	\$1,881,489,000	+\$80,948,000	moderately effective
FY 2006 PARTs				
No PART was performed in FDA during the FY 2006 budget cycle.				

## Narrative

For the FY 2005 PART, OMB decided to evaluate FDA as a single entity and not five programs. FDA senior leadership made a concerted effort to improve the PART score by developing outcome and efficiency goals, reducing the number of performance goals, and implementing management improvements. Based on these actions, OMB gave FDA a rating of moderately effective. Specifically, the FY 2005 PART assessment found:

- FDA has a clear mission and a unique Federal role in protecting public health;
- FDA is well managed, and a has strong and comprehensive strategic planning process;
- FDA's annual performance goals allow for measurement of performance results;
- FDA generally meets most annual performance goals;
- Financial management at FDA is sound; FDA has received a clean audit free of internal material control weaknesses for five consecutive years; and
- FDA is improving collaborative efforts with stakeholders and other Federal agencies.

FDA's senior leadership used integrated performance and financial reports to deliberate and decide on the Agency's approach to preparing FDA's Performance Budget submission. These reports enabled senior managers to understand the FY 2004 funding environment, the projected budget environment in FY 2005, and the cumulative impact of these conditions on the FY 2006 performance budget submission. This information also enabled FDA senior leadership to examine the performance impact under various budget scenarios. The FY 2006 Performance Budget reflects the deliberations of this group, based in large part on the information contained in integrated financial and performance reports.

NOTE: The OMB PART Summary Rating, which follows this summary narrative, contains a correction in the "Actual" column of the Long-term efficiency measure. This number, 2,766, is the correct number. In the FY 2006 President's Budget, this document contains the error.

Program: Food and Drug Administration

**Agency:** Department of Health and Human Services

Bureau: Food and Drug Administration

Rating: Moderately Effective

**Program Type:** Regulatory Based

Last Assessed: 1 year ago

Key Performance Measures from Latest PART	Year	Target	Actual
Long-term Efficiency Measure: Reduce administrative staff	2004	2,855	2,766
	2005	2,623	
	2008	2,623	
Annual Measure: Percentage of new drugs and biologic product reviews completed within 10 months.	2004	90%	
	2005	90%	
	2006	90%	
Long-term Measure: Percentage of medical device submissions that will receive	2001		72%
final decisions within 320 review days.	2005	70%	
	2006	80%	
	2007	90%	

## Recommended Follow-up Actions

Status

Is requesting additional food defense resources to support the Action taken, but achievement of FDA's lab surge capacity targets.

not completed

Will track FDA performance on new long-term outcome goals. Action taken, but

not completed

## Update on Follow-up Actions:

FDA has started efforts to measure performance on long-term outcome goals developed for the FY 2005 PART. For some of these long-term outcome goals, the agency is developing baseline data needed to measure performance improvements. For others, the agency is focusing efforts on improvements in performance and management practices.

Program Funding Level (in millions of dollars)

2004 Actual	2005 Estimate	2006 Estimate
1,695	1,801	1,881